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# Speech and language therapy interventions for children with primary speech and/or language disorders (Protocol)

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[Intervention Protocol]

# Speech and language therapy interventions for children with primary speech and/or language disorders

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## ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To determine the effectiveness of speech and language therapy interventions for children with a primary diagnosis of speech and/or language disorders. The review will focus on comparisons between active interventions and controls.

## BACKGROUND

### Description of the condition

Speech and/or language disorders are amongst the most common developmental difficulties in childhood. Such difficulties are termed 'primary' if they have no known aetiology, and 'secondary' if they are caused by another condition such as autism, hearing impairment, general developmental difficulties, behavioural or emotional difficulties or neurological impairment (Stark 1981; Plante 1998). Although some children have either a primary speech disorder but not a language disorder, or vice versa, these disorders commonly overlap. In addition, interventions in both cases share commonalities; for example, focusing on various elements of the language system and common underlying processes such as attention and listening. Therefore, in both research and intervention, it is difficult to tease speech and language disorders apart.

It is thought that approximately 5% to 8% of children may have difficulties with speech and/or language (Boyle 1996; Tomblin 1997), of which a significant proportion will have 'primary' speech and/or language disorders. The presentation of primary speech and/or language disorders can vary considerably between individuals in terms of severity, pattern of impairment and degree of comorbidity (Bishop 1997). Questions have been raised in recent years as to how 'specific' to speech and language these problems are, but this distinction between primary and secondary difficulties remains clinically useful and is one commonly reported in the literature (Bishop 1997; Leonard 2014; Reilly 2014 and associated papers).

Given the heterogeneity of presentation, there are inconsistencies in terminology for speech and/or language disorders with no agreed diagnostic label. The term 'language disorder', as used in the latest edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5 2013), has been found to be problematic, as it identifies too broad a range of conditions (Bishop 2014). The

term 'specific language impairment' is the most commonly-used diagnostic label, 'specific' referring to the idiopathic nature of the condition. However, this term is problematic in that it suggests difficulties are specific to language only. Disagreements about terminology impede research and clinical processes as well as access to services (Reilly 2014), and differences in diagnostic categories/labels have implications for the current review, meaning that a wide range of different terms are expected across the literature. For the purpose of the current review, however, impairments in speech and language will be referred to as 'speech and/or language disorders', reflecting the possibility that children may have impairment in both or either of these areas.

Primary speech and/or language disorders can affect one or several of the following areas: phonology (the pattern of sounds used by the child), vocabulary (the words that a child can say and understand), grammar (the way that language is constructed), morphology (meaningful changes to words to signal tense, number, etc.), narrative skills (the ability to relate a sequence of ideas), and pragmatic language (the ability to understand the intended meaning of others and to communicate effectively in conversation (Adams 2012)). As regards the current review, the majority of these affected areas may be categorised as a 'language' outcome, with 'phonology' categorised as a separate outcome. It is unclear whether primary speech and/or language disorders represent varying levels of a single condition, or a number of different conditions with diverse aetiologies but similar presenting patterns (Law 1998; Tomblin 2004).

There is little consensus on the aetiology of primary speech and/or language disorders but there is evidence of a number of associated risk factors, including medical difficulties (for example, being born small for gestational age), and motor skill deficits (Hill 2001). There is increasing evidence of genetic underpinnings of speech and/or language disorders (SLI Consortium 2004; Bishop 2006); the links appear to be stronger for expressive language difficulties than receptive language difficulties (Kovas 2005). There remain questions as to the nature of the role of environmental factors, whether distal (for example, socioeconomic status and maternal education) or proximal (for example, parent-child and peer-peer interaction and relationships) as causes of primary disorder, or whether these are factors affecting outcomes (mediators). Twin studies have so far suggested that heredity plays an increasingly strong role, especially as the child moves through primary school and especially for less socially-disadvantaged children, but that environmental factors can have a relatively important role to play in the early years, and that marked language difficulties between higher and lower social groups are identifiable from very early on in children's development and tend to persist (Bradbury 2015). It is likely that these risk factors act in a cumulative fashion to increase the severity of the presenting disorder (Aram 1980) and are relevant when it comes to affecting access to educational and therapeutic resources.

Primary speech and/or language disorders can have far-reaching implications for the child and his/her parent or carer in both the short and the longer term. Studies indicate that they may have adverse effects upon school achievement (Aram 1984; Baker 1987; Bishop 1990; Catts 1993; Tallal 1997). It has recently been reported that "approximately two children in every class of 30 pupils will experience language disorder severe enough to hinder academic progress" (Norbury 2016). They may also be associated with comorbid social, emotional and behavioural problems (Huntley 1988; Rice 1991; Rutter 1992; Stothard 1998; Cohen 2000; Conti-Ramsden 2004), and with peer interaction difficulties (Murphy 2014). Children with primary speech and/or language disorders can also have long-term difficulties that persist to adolescence and beyond (Rescorla 1990; Haynes 1991; Johnson 1999), with some 30% to 60% experiencing continuing problems in reading and spelling, and with early difficulties predicting adult outcomes in literacy, mental health and employability (Law 2009a).

## Description of the intervention

Interventions for children identified as having primary speech and/or language disorders include a variety of practices (methods, approaches, programmes) that are specifically designed to promote speech and/or language development or to remove barriers to participation in society that arise from a child's difficulties, or both. Assessment of eligibility for intervention includes a combination of standardised assessment (where available), observations of linguistic and communicative performance, and professional judgement. Interventions are usually time limited and can be delivered by any professional group, but usually involve input from language specialists, most notably speech and language therapists/pathologists. The criteria for inclusion in such interventions commonly includes some reference to the specific or the primary nature of the language difficulty experienced by the children concerned - that is, it is not associated with low non-verbal performance - and this allows for a focus on speech and language characteristics rather than a broader range of skills.

Interventions for children with speech and/or language disorders may be carried out directly or indirectly, and in a range of settings, such as the home, healthcare service provision, early years setting (nursery/school), school or private practices, by the specialist professionals themselves or through proxies such as parents, teachers or teaching assistants. There are also examples where interventions are delivered through peers in school.

Direct interventions focus on the treatment of the child individually, or within a group, depending on the age and needs of the children requiring therapy and the facilities available. In group treatments, it is thought that children benefit from the opportunities to interact and learn from one another.

Indirect interventions are often perceived to be more naturalistic in approach, allowing adults that are already within the child's environment to facilitate communication. Traditionally, these ap-

proaches create an optimum communicative environment for the child by promoting positive parent-child interaction. Indirect approaches are increasingly being employed within a range of settings where speech and language therapists train professionals and carers who work with the children, and provide programmes or advice on how to maximise the child's communicative environment and enhance communicative attempts.

Parents are often actively engaged in delivering interventions to younger children but tend to be less actively involved in the administration of the intervention as the child gets older. Many intervention models target behaviours using play to enhance generalisation. Interventions for children with primary speech and/or language disorders would, in many cases, meet the criteria for being a complex intervention (Craig 2008), being made up of a number of elements that vary according to both the theoretical assumptions behind the intervention and the perceived needs of the child.

The majority of interventions involve the training of specific behaviours (speech sounds, vocabulary, sentence structures) accompanied by reinforcement. Most commonly this involves rewards of some form (stickers, tokens and, most often, praise). The assumption behind overt behavioural techniques is that language or speech can explicitly be taught and that gaps in the child's skills can be filled by instruction. In the past twenty years, most therapy has shifted from explicit training paradigms to those based on social learning theory, which assumes that children learn most effectively if they are trained within a social context (Miller 2011).

As the child gets older the emphasis of interventions shifts towards a more functional approach, whereby children are taught skills that are most useful for them at that moment. This functional shift often involves a move from explicit instruction to a more 'meta-cognitive' approach whereby the therapist will encourage the child to reflect on what they hear and then adopt it into their own repertoire. Often the therapist will present the child with alternatives and encourage them to make judgements based on their intrinsic grammatical or phonological knowledge. It is assumed that the process of making a judgement increases the child's chances of modifying their language and/or speech performance. 'Constructivist' or usage-based explanations represent a new direction from a linguistic perspective (Childers 2002; Riches 2013).

Speech and/or language therapy interventions vary in duration and intensity depending on the resources available, the perceived needs of the child, and policies of different speech and/or language therapy and educational services. The intensity and the duration of typical therapy interventions have yet to be evaluated systematically (Warren 2007), although both of these issues have been raised as potentially important determinants of outcomes (Law 2000; Hoffman 2009). In practice, some interventions are of short duration and relatively low intensity, for instance, six hours over a year. It is common for these short durations of intervention to be offered in 'blocks' of treatment, commonly once a week for a six-week period. This may then be repeated depending on a child's progress - although there is no specific evidence underpinning this approach. In other instances, especially in schools, interventions may be delivered on a daily basis over a longer period. On balance, however, most speech and/or language interventions tend to be relatively short (less than 20 hours in total).

Treatment goals vary considerably depending on the perceived difficulty that the child is experiencing. While the focus is often on aspects of expressive language, many studies also focus on receptive language ability or verbal comprehension, and in the last decade there has been an increasing emphasis on pragmatic language difficulties (the way children use language with others). Treatment goals may focus on specific aspects of language or address a number of aspects of language in combination. For many speech and language therapists, the child's social skills and their ability to integrate with peers and negotiate the curriculum are key outcomes.

There have been a number of recent developments in intervention for children with primary speech and/or language disorders, listed as follows.

1. An increased use of computerised intervention packages, and most recently 'apps' (short for computerised 'application'), in education.
2. A move towards meta-cognitive or meta-linguistic interventions, especially for older children and often with a view to enhancing comprehension. These emphasise the child making judgements based on their underlying linguistic knowledge, and often use other, readily recognisable supports (that is, colour and shape).
3. Increased emphasis on universal or public health interventions whereby speech, and especially language, interventions are provided for whole populations using key messaging to parents and training public health professionals (for example, Health Visitors in the UK) (Law 2013).
4. Increased focus on comorbidity, for example, the relationship between language skills and socio-emotional skills, and whether interventions addressing the former may have outcomes relevant to the latter (Law 2009b).

## How the intervention might work

There are some explicit elements in the mechanism of change that can be identified and that are likely to help identify the 'active ingredients' of any intervention both in terms of immediate and longer-term benefits.

### The delivery agent

Interventions, especially those for younger children, often involve the child's parents or caregivers. This creates an optimum communicative environment for the child by promoting positive parent-child interaction. It can increase parental knowledge about speech and language development, including how they might target their child's language development at home. It also helps them provide

'carry over' or generalisation at home and then 'maintenance' over time. Similarly, training teachers and teaching assistants to carry out the intervention tasks has the potential to widen the child's opportunities to practice new skills. Targeted interventions are likely to be delivered by specialist practitioners such as a speech and language therapist/pathologist. Evidence does suggest that it may be less the category of person that is key here than the commitment of parents and the experience and training of the practitioner that makes the difference. This may be especially true for aspects of grammar and phonological development, where the specialist skills of the speech and language therapist/pathologists are likely to be of paramount importance.

### The context of delivery

Intervention for children with speech and/or language disorder is carried out in a number of different contexts: the home, the clinic, the nursery/early years setting/kindergarten, the school, etc. Many of the interventions reported in earlier studies were 'clinical' in focus, in the sense that they were carried out in a clinic separate from school, perhaps with the parents in attendance or actively engaged. In practice, while this may still be true for many children when they first encounter specialist services, this type of 'pull out' model is much less common, and children are seen within settings where they spend most of their time. The rationale is that the context in which children learn language is critical for their outcomes and that maximising the most appropriate sort of intervention in the right environment is more likely to be effective in the long run than very specific intervention led solely by an adult 'expert'. That said, there may well be a case for this more specific, one-to-one intervention, especially with children who have more pronounced problems.

In recent years there has been an increased use of computer-delivered intervention, effectively a mediated version of the adult 'expert' model. Computerised interventions work by providing very explicit links between the stimulus and the reward within the context of the game format in which they are presented. Due to their similarity to non-educational computer games with which children are often familiar, these interventions are considered to have a positive effect on a child's motivation and engagement. Such approaches have been used widely where there has been limited access to specialist provision.

### The intervention technique

Speech and language therapists commonly use a range of behavioural techniques, including imitation, modelling, repetition and extension. These draw the child's attention to the structure and the content of the speech or language input (or both), and the input is often presented at a developmental level a little ahead of that of the child. Stimuli are commonly repeated many times to draw the child's attention to the correct form. It is assumed that practice is one of the cornerstones of reinforcement and that repetition makes it easy for the child to learn what they have not otherwise acquired. Key to all intervention is building the child's motivation to speak.

Children with speech and/or language disorder are often described as having poor auditory skills. There has been an ongoing discussion as to whether the child's auditory skills are the key underlying problem or whether the breakdown is primarily linguistic in nature (Bishop 2005), and there is individual variability in auditory processing skills, which must be recognised prior to intervention delivery in order to personalise intervention to individual strengths and weaknesses. Nevertheless, activities designed to heighten the child's awareness of their auditory environment are common components of most interventions and may be a key ingredient in effective interventions.

Children with speech and/or language disorders are often thought to have strengths in their visual, relative to their auditory, processing and for this reason their visual skills are used to compensate for their other difficulties. Within the child's most common contexts for learning, the classroom and the home environment, information is often presented visually (NCLD 1999). In speech and language interventions, widespread use is made of pictorial support materials and visual timetables to help children make better use of auditory material. In some cases, interventions are supported by manual signing systems (for example, Makaton or Paget Gorman).

### The dosage

Frequency, intensity and duration of interventions vary considerably. It may be that the amount of intervention is key to an intervention's success; however, variability between interventions and outcomes means it is difficult to make recommendations about optimal dosage (Zeng 2012). It may be that for some outcomes that are measured continuously, such as vocabulary, there may be a simple dosage or response effect - the more intervention received, the greater the vocabulary learned - but for others, such as specific grammatical structures where outcomes are more focussed, intensity may be more functionally important than duration. Care has to be taken in adopting specific programmes to retain the recommended dosage, and to not assume that reducing the amount of intervention for pragmatic, cost-related reasons is likely to lead to the same effects.

### The outcome

On the one hand, the intervention is most likely to 'work' if the outcome directly reflects the intervention that the child receives. On the other, it is often considered more desirable and indeed more robust if effects can be demonstrated on standardised omnibus language tests. Consequently, an intervention may be said to work more effectively on very specific outcomes and may work less effectively on population, standard, norm-referenced measures, which have commonly not been designed to capture change.

### Adverse effects

There are no known adverse effects of the interventions concerned. It is important to acknowledge that there are potential implications in terms of raised anxiety in parents who are made aware that there is concern about their child's speech and/or language development. There could also be risks associated with children being taken out of their routine schooling (with resultant reduction in exposure to the curriculum) to attend specialist sessions if the sessions are found to be of uncertain benefit.

## Why it is important to do this review

This protocol updates a previously published systematic review (Law 2003a), but is substantively different in that it excludes studies comparing interventions with alternative interventions - so called 'head-to-head' studies - so that this review will only report on treatments compared to no treatment or to a placebo. This has been done to aid interpretation of the results. An array of different alternative interventions, where there is rarely more than one version of any given alternative, make it difficult to report outcomes in a coherent fashion. Studies with alternative intervention comparison groups are often very different in terms of the treatment received. This increases heterogeneity and makes the combination of effect sizes problematic. Each alternative intervention comparison would need to be reported separately. It may be that in future iterations of this review, or in other reviews, specific head-to head comparisons do become feasible.

There is a strong case for retaining the focus on interventions that include a broad range of language functions across childhood, to act as a benchmark in the field, although care needs to be taken to test for compatibility.

Previous reviews have largely been narrative in nature and thus prone to bias (Goldstein 1991; Enderby 1996; Law 1997; McLean 1997; Gallagher 1998; Guralnick 1998; Olswang 1998; Yoder 2002; McCauley 2006; Leonard 2014). Two systematic reviews (Nye 1987; Law 1998) were published prior to the publication of the first Cochrane review in the field (Law 2003a). A number have followed it, covering specific subpopulations or practice contexts; for example, interventions for preschool children only (Schooling 2010), educational contexts (Cirrin 2008), receptive language impairments (Boyle 2010), parent-child interaction (Roberts 2011), grammatical development (Ebbels 2013), computerised interventions (Strong 2011), late talkers (Cable 2010), language or literacy (Reese 2010), and vocabulary learning in typically developing children (Marulis 2010).

The original Cochrane review triggered a number of discussions about whether the approach employed in the review was the most effective, given the constraints associated with the subject domain and effectively captured in the Medical Research Council (MRC) guidelines (Craig 2008). (See Pring 2004; Johnston 2005; Law 2005a; Garrett 2006; Marshall 2011). While clinical guidelines to direct practice in speech and language therapy do exist (RCSLT 2005; Johnson 2006), there remains little in the way of specific guidance on what type of intervention to offer children with primary speech and language impairment. This review has the potential to help inform such guidance where evidence is both sufficiently robust and sufficiently strong to warrant such recommendations.

# OBJECTIVES

To determine the effectiveness of speech and language therapy interventions for children with a primary diagnosis of speech and/or language disorders. The review will focus on comparisons between active interventions and controls.

# METHODS

## Criteria for considering studies for this review

### Types of studies

We will include randomised controlled trials (RCTs).

### Types of participants

Children and adolescents up to the age of 18 years who have been given a diagnosis of primary speech and/or language disorder by a speech and language therapist/pathologist, child development team or equivalent.

#### Exclusion criteria

We will exclude studies if there is clear evidence that children have learning disabilities, hearing loss, neuromuscular impairment or other primary conditions of which speech and/or language disorders are commonly a part. Children whose difficulties arise from stuttering or whose difficulties are described as learned misarticulations (for example, lateral /s/ (lisp) or labialised /r/ (rhotic r)) will also be excluded from this review. In addition, we will exclude studies that focus on bilingual or multilingual children as a feature of the study, and studies in which training of literacy skills is the primary focus of the study. We will also exclude from the review studies that include infants or babies.

### Types of interventions

Any type of therapy intervention, of any duration and delivery method, compared with delayed ('wait-list') or no-treatment controls or general stimulation conditions. General stimulation conditions include, for example, studies where control children are assigned to a control condition designed to mimic the interaction found in therapy without providing the target linguistic input. These conditions may be cognitive therapy or general play sessions that do not focus on the area of interest in the study.

We will include therapy interventions designed to improve an area of speech and/or language functioning concerning either expressive and receptive phonology (production and understanding of speech sounds, including recognising and discriminating between speech sounds and awareness of speech sounds, for example, rhyming and alliteration), expressive or receptive vocabulary (production or understanding of words), expressive or receptive syntax (production or understanding of sentences and grammar), or pragmatic language.

### Types of outcome measures

We will use formal standardised tests, criterion-referenced tests, parent reports and language samples. Within each of these categories there are many different measures, and different measures assess different areas of speech and language. Some examples include the Clinical Evaluation of Language Fundamentals (CELF, Semel 1995), within which both language and phonology are measured, the New Reynell Developmental Language Scales (NRDLS, Edwards 2011) and the Children's Communication Checklist (CCC, Bishop 2003), which both measure language but not phonology, and the Diagnostic Evaluation of Articulation and Phonology (DEAP, Dodd 2006), which measures speech and phonology.

Intervention studies in this area commonly report more than one outcome (reflected in a range of different measures and measures that assess different areas of speech and language) and it may not always be explicit whether such outcomes are primary or secondary. In such cases we will make a judgement as to which of the outcomes are most closely linked to the goal of the intervention specified in the background to the study in question.

Outcomes used in the review must be matched to the participants' areas of difficulty (for example, we will not include receptive language outcomes in the review if one of the inclusion criteria for the study was that participants had to have receptive language within normal limits).

#### Primary outcomes

1. Language.
2. Phonology.
3. Adverse effects. We will monitor studies for adverse effects. These are likely to be in the form of increased response of control relative to treatment groups, raised parental anxiety, and high dropout rates reflecting poor acceptability or parental dissatisfaction.

#### Secondary outcomes

1. Composite language measures.
2. Expressive vocabulary.
3. Expressive syntax.
4. Receptive vocabulary.
5. Receptive syntax.
6. Expressive phonology.
7. Phonological awareness (including phonological recognition and discrimination).

We will use these primary and secondary outcomes to populate the 'Summary of findings' table.

## Search methods for identification of studies

### Electronic searches

We will search the sources listed below for all available years. We will not limit our search by language, date of publication or publication status, and will seek translations where necessary.

1. Cochrane Central Register of Controlled Trials (CENTRAL; current issue) in the Cochrane Library, and which includes the Cochrane Developmental, Psychosocial and Learning Problems Specialised Register.
2. MEDLINE Ovid (1948 onwards).
3. MEDLINE E-pub ahead of print Ovid (current issue).
4. MEDLINE In-Process and Other Non-Indexed Citations Ovid (current issue).
5. Embase Ovid (1980 onwards).
6. CINAHL EBSCOhost (Cumulative Index to Nursing and Allied Health Literature; 1937 onwards).
7. ERIC EBSCOhost (Education Resources Information Center; 1966 onwards).
8. PsycINFO Ovid (1872 onwards).
9. LILACS (Latin American and Caribbean Health Sciences Literature; lilacs.bvsalud.org/en).
10. SpeechBITE (speechbite.com).
11. ProQuest Dissertations & Theses UK & Ireland (1950 onwards).
12. Conference Proceedings Citation Index - Science Web of Science (CPCI-S; 1990 onwards).
13. Conference Proceedings Citation Index - Social Science & Humanities Web of Science (CPCI-SS&H; 1990 onwards).
14. *Cochrane Database of Systematic Reviews* (CDSR; current issue) in the Cochrane Library.
15. Epistemonikos (epistemonikos.org).
16. ClinicalTrials.gov (clinicaltrials.gov).

17. World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; who.int/trialsearch).

The search strategy for MEDLINE is in Appendix 1. We will modify this search strategy, as appropriate, for all other databases and report these additional search strategies in an Appendix in the full review.

### Searching other resources

We will check the reference lists of included studies and relevant reviews identified by the electronic searches for further studies. We will also contact key authors in the field for information about ongoing or unpublished studies that we may have missed. In addition, we will search The Communication Trust's What Works database of interventions (thecommunicationtrust.org.uk/whatworks).

## Data collection and analysis

### Selection of studies

Review authors, working in pairs (JL, JAD and JJVC), will independently select potentially-relevant studies for inclusion from the titles and citations or abstracts list generated by the search. Review authors will not be blinded to the name(s) of the trial author(s), institution(s) or publication source at any level of review.

Full-text copies of all reports will be obtained and, if necessary, translated in order to assess eligibility. Two review authors (JL, JAD and JJVC, working in pairs) will independently assess reports against the inclusion criteria established under Criteria for considering studies for this review. When information is missing, we will contact trial investigators, where possible. Studies that have been identified by mutual consent will be included in the review. Studies for which multiple reports appear will be categorised as 'included' or 'excluded' only once, and associated publications listed as secondary references. We will document all work in accordance within PRISMA guidance (Moher 2009), and produce a flowchart of the process.

### Data extraction and management

Two review authors (JL, JAD and JJVC) will independently extract data from reports of all eligible studies using a piloted form covering the following.

1. Design and methods (including information necessary to complete 'Risk of bias' tables as per the *Cochrane Handbook for Systematic Reviews of interventions* (Higgins 2011a)).
2. Participants (including demographics/baseline characteristics such as age, gender, socioeconomic status and severity of speech and language difficulty).
3. Interventions (setting, focus, method of delivery and duration).
4. Outcome measures and associated outcome data, paying particular attention to modifications to scales, identity of assessor and timing of measurement.

We will resolve uncertainty and disagreement through discussion until consensus is reached. In addition, we may request further information from trial investigators, to ensure a given study meets inclusion criteria.

We will use endpoint scores (or 'post-intervention', 'Time 2' or 'T2' scores) as our preferred treatment effect measure. When necessary, we will code multiple reports of a single study onto a single data extraction form. We will use a single Excel sheet to manage all numerical data from all forms.

### Assessment of risk of bias in included studies

At least two review authors (JL, JAD and JJVC) will independently assess the risk of bias within each included study according to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). Review authors will independently assess the risk of bias within published reports of each included study across the seven domains described below and assign ratings of 'low', 'high' or 'unclear' risk of bias.

#### 1. Sequence generation

We will determine whether studies used computer-generated random numbers or a table of random numbers, drew lots or envelopes, or relied on coin tossing, shuffling cards, or throwing dice.

1. Low risk of bias: the study authors explicitly stated that they used one of the above methods.
2. High risk of bias: the authors did not use any of the above methods.
3. Unclear risk of bias: there is no information on the randomisation method or it is not clearly presented.

#### 2. Allocation concealment

We will evaluate whether investigators and participants could foresee assignments before screening was complete and consent was given.

1. Low risk of bias: researchers and participants were unaware of future allocation to treatment conditions.
2. High risk of bias: allocation was either not used or was not concealed from researchers before eligibility was determined, or was not concealed from participants before consent was given.
3. Unclear risk of bias: information regarding allocation concealment is not known or not clearly presented.

#### 3. Blinding of participants and personnel

Neither participants nor treatment providers (therapists) can be kept blind to the intervention condition in studies of this nature, and the resultant risk of bias will be recorded as 'high: assessors

were not blind to treatment condition' for these component groups for this domain.

#### 4. Blinding of outcome assessment

We will address the issue of whether or not outcomes were assessed by self-report or whether objective assessors and coders of measures were employed and, if so, what steps were taken to blind them to treatment conditions.

1. Low risk of bias: assessors were blind to the outcome assessment.
2. High risk of bias: assessors were not blind to the outcome assessment.
3. Unclear risk of bias: information on the blinding of assessors is unclear or unavailable from study authors.

#### 5. Incomplete outcome data

We will identify the presence of incomplete outcome data as follows.

1. Low risk of bias: there are no dropouts/exclusions; there are some missing data but the reasons for missing data are unlikely to be related to the true outcome; or missing data are balanced in proportion across intervention groups, with similar reasons for missing data across groups.
2. High risk of bias: there is differential attrition across groups, reasons for dropout are different across groups, or there was inappropriate application of simple imputation (for example, assuming certain outcomes, last observation carried forward (LOCF), etc.).
3. Unclear risk of bias: the attrition rate is unclear or authors state that intention-to-treat analysis was used but provide no details.

#### 6. Selective outcome reporting

To assess reporting bias, we will attempt to collect all study reports and protocols and trial registration information, if possible, and will track the collection and reporting of outcome measures across all available reports for each included study.

1. Low risk of bias: all outcome measures and follow-ups are reported.
2. High risk of bias: data from some outcome measures are not reported.
3. Unclear risk of bias: it is not clear whether all data collected by study authors were reported.

#### 7. Other sources of bias

**Performance bias**

We will assess whether there were treatment differences between groups other than the main intervention.

1. Low risk of bias: there were no treatment differences between groups other than the main intervention.
2. High risk of bias: there were treatment differences between groups other than the main intervention.
3. Unclear risk of bias: it is unclear whether there were differences between groups or this information was not available from study authors.

We will attempt to use the judgement of 'unclear risk of bias' as infrequently as possible.

**Publication bias**

We will make a concerted effort to identify unpublished RCTs in the field of interventions for speech and/or language disorders in order to establish whether there is publication bias.

### Measures of treatment effect

We will use endpoint scores (or immediate 'post-intervention', 'Time 2' or 'T2' scores) as our preferred treatment effect measure. These data may be binary or continuous.

#### Binary data

Although most of our prespecified outcomes are typically assessed with continuous measures, we anticipate some investigators may choose to dichotomise scale data into 'improved' or 'not improved'. In such cases, we plan to calculate odds ratios (ORs) with 95% confidence intervals (CIs).

#### Continuous data

When studies have used the same continuous outcome measure we will calculate mean differences (MDs) with 95% CIs. When studies have used different outcome measures to assess the same construct (for example, by using different scales to assess syntactic structure), we will calculate standardised mean differences (SMDs) and 95% CIs.

We will analyse and present conceptually-distinct outcomes separately and will describe the properties of all scales used in a table, so that decisions concerning appropriate categorisation will be transparent to readers.

In the event that change scores are reported and endpoint data are not available, we will pool the data in Review Manager 5 ( RevMan 2014), using the MD (provided all instruments used for that outcome are the same), as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (section 9.4.5.2, Deeks 2011). If outcome scales differ, we will present change score data separately, as combining data using SMD is unfeasible.

## Unit of analysis issues

### Cluster-randomised studies

Although it is likely that most of the interventions delivered for children with speech and language impairments will have randomised children at the individual level, there is a possibility that children will be allocated at a service level (clinic/school/class); so-called cluster-randomised studies. Cluster randomisation reduces the risk of contamination across those delivering the intervention. If we identify cluster-RCTs, we will adhere to the guidance on statistical methods for managing data from cluster-RCTs provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (section 16.3, Higgins 2011b). We will check that adequate adjustments for clustering were made for estimates of treatment effects. If not, we will seek to extract or calculate effect estimates and their standard errors as for a parallel-group trial, and adjust the standard errors to account for the clustering (Donner 1980). This requires information on an appropriate intraclass correlation coefficient (ICC); an estimate of the relative variability in outcome within and between clusters (Donner 1980). If this information is not available in the relevant report, we will request it from the study authors. If this is not available or we receive no response, we will use external estimates obtained from studies that provide the best match on outcome measures and types of clusters from existing databases of ICCs (Ukoumunne 1999), or other studies within the review. If we are unable to identify an appropriate ICC, we will perform sensitivity analyses using a high ICC of 0.10, a moderate ICC of 0.01 and a small ICC of 0.00 (see Sensitivity analysis). These values are rather arbitrary but, as it is unlikely that the ICC is actually 0, it is preferable to use them to adjust the effect estimates and their standard errors. We will combine the estimates and corrected standard errors from cluster-RCTs with those from parallel designs using the inverse variance method in RevMan 2014.

### Multiple treatment arms

We are aware that investigators frequently attempt to test many interventions or variations on similar interventions within the context of a single trial, even with a small sample. In such circumstances, where this is deemed appropriate by the review team, we may combine multiple eligible interventions tested within the same trial. This will be carried out using a standard formula for this purpose, as indicated in section 7.7.3.8 in the *Cochrane Handbook for Systematic Reviews of Inverventions* (Higgins 2011c). This formula for combining multiple arms is located in Table 7.7a within the Handbook, and can be used to combine numbers into a single sample size, mean and standard deviation for each intervention group. Where this has been carried out we will make it explicit in the review's narrative.

### Cross-over trials

With any educational or behavioural intervention such as speech and language therapy, true cross-over trials are extremely unlikely. Should they arise, we are likely to treat them as parallel-group studies and extract data at the point of first cross-over. What is more common in this field are pseudo cross-over studies of multicomponent interventions, in which one part of an intervention is delivered before the other in one intervention arm, and the second part delivered first in a second treatment arm (this resembles a cross-over trial but is, in effect, a study of 'order of treatment' effect). As the review excludes head-to-head trials, we will only include pseudo cross-over studies with a third 'no treatment', 'waiting control' or 'treatment-as-usual' arm. Therefore, we will extract endpoint data for both groups (after all parts of the multicomponent treatment are delivered).

## Dealing with missing data

We will make every effort to contact the original investigators of included studies to gather information missing in the written reports.

For studies in which dropout is high or differently distributed between groups within the study, or both, we plan to conduct a Sensitivity analysis in which we will exclude such studies. We will not conduct any imputation of our own.

## Assessment of heterogeneity

We anticipate clinical and methodological heterogeneity in included studies for a number of reasons. Different criteria are applied to children entering studies, sometimes making comparability across studies difficult. Similarly, different measures of speech and language are used to identify children for inclusion in studies and to measure outcomes. Finally, as indicated above, it is not uncommon for children identified with speech and/or language disorders to experience other 'comorbid' conditions such as other developmental difficulties or socioemotional problems. In some cases these are recorded; in others, it is unclear whether children experience such difficulties or not. These differences can make it challenging to compare across studies. To account for these differences, we will record assessment thresholds and potential comorbidity in our data extraction form and carry out subgroup analyses comparing groups of studies using the same or different assessments, more or less inclusive criteria, and with and without comorbidities.

We will explore heterogeneity by conducting subgroup analyses in RevMan 2014. Characteristics of heterogeneity to be explored include the presence of more than one type of language impairment based on included outcomes in the current review (for example, expressive language impairment and phonological impairment), and the presence of an additional behaviour impairment (for example, attention deficit hyperactivity disorder, or behavioural, emotional and social difficulties).

We will assess statistical heterogeneity using the Chi² test for heterogeneity and a P value of 0.10 to account for low power due to small sample size. In addition, we will assess heterogeneity through visual inspection of forest plots (considering the magnitude of direction and effect) and the I² statistic (Higgins 2003). We will consider values between 50% and 90% to represent substantial heterogeneity. As we will be using the random-effects model we will also report tau² as a measure of between-study variance. We will assess clinical and methodological heterogeneity by meta-regression, using subgroups to explore how categorical study characteristics are associated with the intervention effects in the meta-analysis.
See Subgroup analysis and investigation of heterogeneity.

### Assessment of reporting biases

We plan to investigate the possibility of reporting biases, including publication bias, by assessing funnel plots for asymmetry where 10 or more studies report on the same outcome (Egger 1997; Sterne 2001; Deeks 2005). Asymmetry could be due to publication bias or to a genuine relationship between trial size and effect size (Sterne 2000). We will examine clinical variation of the studies to explore asymmetry.
We will diligently search for trial protocols for all included studies within the review; however, we are conscious that the trend to register protocols for trials has been less robust than in more traditionally 'medical' fields over time.

### Data synthesis

We will only combine data where the intervention and the measurement are conceptually the same; primarily this will focus on the participant and intervention characteristics and study outcome. For example, all parent-child interventions targeting and measuring expressive language may be combined. After this first pass, we will then make a judgement as to whether the interventions and measurements included in other studies are sufficiently similar to compare. We will base our decision to perform a quantitative synthesis of the data on whether the method of delivery (for example, parent, clinician) and outcome (for example, language, expressive vocabulary) of the intervention are the same constructs across studies. We will not combine data where interventions fall into different delivery or measurement categories.
Where appropriate, we will carry out data synthesis in RevMan 2014, using inverse-variance weighting. Differences in apparent intervention effects are considered as random effects (as it is less understood why such differences occur). If we are unable to conduct a meta-analysis, we will carry out a narrative review of data.

### Subgroup analysis and investigation of heterogeneity

We plan to conduct subgroup analyses to explore the impact of the study characteristics listed below on the results.

1. The role of administrator. Studies are likely to outline interventions that are delivered by different parties, using either clinicians, parents, computers or peers as the administrators. We will examine studies using different administrators separately and compare the results to the primary analysis.
    i) Subgroup one: administrator versus no intervention:
        a) intervention versus no intervention;
        b) parent versus no intervention;
        c) computer intervention versus no intervention; and
        d) peer intervention versus no intervention.
    ii) Subgroup two: administrator versus general stimulation:
        a) intervention versus general stimulation;
        b) parent intervention versus general stimulation;
        c) computer intervention versus general stimulation; and
        d) peer intervention versus general stimulation.
2. The role of age of the child. We plan to consider the effect of interventions within the following subgroups, should data be available:
    i) preschool children (birth to 4 years of age);
    ii) primary school children (5 years to 11 years of age); and
    iii) older children (12 years of age and above).
3. The impact of comorbid difficulties. We plan to account for comorbidity by comparing groups of studies with the following characteristics:
    i) comorbid disorders (e.g. behaviour disorders, autism spectrum disorders); and
    ii) level of assessment (impairment cut-off points).
4. Variance in degree of heterogeneity. We plan to account for variance in degree of heterogeneity of language disorders by comparing studies in which more than one language impairment is present.

### Sensitivity analysis

We plan to conduct sensitivity analyses to explore the effects on the results of including and excluding the types of studies below.
1. Studies that do and do not have an explicit process for their randomisation.
2. Studies where blinding of outcome assessors was inadequate or not attempted.
3. Studies in which dropout is high (30%), or differently distributed between groups within the study, or both.
In addition, in cluster-randomised studies where we are unable to identify an appropriate ICC, we will perform sensitivity analyses using a high ICC of 0.10, a moderate ICC of 0.01 and a small ICC of 0.00.

### 'Summary of findings' table

We will present a 'Summary of findings' table(s) within the completed review. We will use GRADEpro 2014 to prepare the 'Summary of findings' table(s), as needed. We plan to assess the overall quality of the evidence for each outcome as 'high', 'moderate', 'low' or 'very low' according to the GRADE approach (Schünemann 2011). We will consider the criteria below.

1. Impact of risk of bias of individual trials.
2. Precision of pooled estimate.
3. Inconsistency or heterogeneity (clinical, methodological and statistical).
4. Indirectness of evidence.
5. Impact of selective reporting and publication bias on effect estimate.

We will use our primary and secondary outcomes (Types of outcome measures) to populate the 'Summary of findings' table(s).

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* *Indicates the major publication for the study*

# APPENDICES

## Appendix 1. MEDLINE search strategy

1 exp Communication Disorders/
2 (speech adj5 disorder$).tw,kf.
3 (speech adj5 delay$).tw,kf.
4 (speech adj5 impair$).tw,kf.
5 (language adj5 disorder$).tw,kf.
6 (language adj5 delay$).tw,kf.
7 (language adj5 impair$).tw,kf.
8 dysglossia.tw,kf.
9 anomia.tw,kf.
10 Aphasia.tw,kf.
11 articulation.tw,kf.
12 echolia.tw,kf.
13 rhinolalia.tw,kf.
14 (mute or mutism).tw,kf.
15 "central auditory processing disorder".tw,kf.
16 "semantic-pragmatic disorder".tw,kf.
17 or/1-16
18 speech therapy/
19 language therapy/
20 myofunctional therapy/
21 (speech adj5 (patholog$ or screen$ or therap$)).tw,kf.
22 speech train$.tw,kf.
23 (language adj5 (patholog$ or screen$ or therap$)).tw,kf.
24 language training.tw,kf.
25 ((grammar or grammatical) adj5 (facilitation or intervention$ or program$ or teach$ or therap$ or train$)).tw,kf.
26 ("Active Listening for Active Learning" or "Broad Target Recast" or "Core Vocabulary" or "Cycles Approach" or "Cycles for Phonology" or Earobics or "Electropalatography" or "Fast ForWord " or "Focussed Auditory Stimulation" or "Gillon Phonological Awareness Programme" or "Hanen" or "Let's Learn Language" or "Lexicon Pirate" or "Lidcombe Programme" or "Linking Language" or "LINK-S" or "Little Talkers" or "Makaton" or " Maximal Oppositions" or "Meaningful minimal contrast therapy " or "MMCT" or "Milieu Teaching" or "Milieu Therapy" or "Morpho-syntactic" or "Multiple Opposition Therapy").tw,kf.
27 ("Naturalistic Speech Intelligibility Training " or "Non-Linear Phonology Intervention " or "Non-speech Oro-motor Exercise " or "Nuffield Dyspraxia Programme " or "Nuffield Early Language Intervention " or "Oral Language Programme" or "Phoneme Factory " or "Phonology with Reading Programme " or "Picture Exchange System " or "Pre-school Autism Communication Therapy " or PACT or "Psycholinguistic Framework " or "Rapid Syllable Transition Treatment" or "Shape Coding" or "Social Communication Intervention Programme" or "Social Stories" or "Strathclyde Language Intervention" or "Talk Boost" or "Talking Time" or "Thinking Together" or "Visualising and Verbalising").tw,kf.
28 or/18-27
29 17 and 28
30 exp Speech Disorders/th,rh
31 exp Language Disorders/th,rh
32 Speech Therapy/mt
33 Language Therapy/mt
34 or/30-33
35 29 or 34
36 exp Child/
37 Infant/
38 adolescent/

39 (child$ or infant$ or baby or babies or toddler$ or boy$ or girl$ or pre-school$ or preschool$ or kindergarten$ or kinder-garten or teen$ or adolescen$ or schoolchild$ or schoolboy$ or schoolgirl or young people or youth$).tw.
40 or/36-39
41 35 and 40
42 randomised controlled trial.pt.
43 controlled clinical trial.pt.
44 randomi#ed.ab.
45 placebo$.ab.
46 drug therapy.fs.
47 randomly.ab.
48 trial.ab.
49 groups.ab.
50 or/42-49
51 exp animals/ not humans.sh.
52 50 not 51
53 41 and 52

## Appendix 2. Data extraction form

Author and date of paper/publication/thesis:
Journal (or other source):
Which comparison?

1. Speech and language therapy (SLT) versus nothing or wait-list control (WLC); or
2. SLT versus general stimulation.

Country (try to include state/province or city, or both, as well):
Setting (for example, school, clinic):
Number of participants at randomisation and at completion:
Unit of allocation:
Age at entry:
Study mix, for example, socioeconomic status (SES):
Gender mix:
Inclusion criteria (severity cutoff):
Intervention:
Target area of intervention:
Who delivers intervention?
How often? How long?
Comparator group (as above):
Length of follow-up (note assessment points):
All outcomes measured (include scale information):
Outcomes used within this review / chosen for comparison:

1. At the level of overall development, for example, phonological maturity or expressive language?
2. At the level of disability, for example, improvement in intelligibility or consonant improvement in speech?

Results (use table below, state follow-up point from which data are taken)
*Expand / copy as necessary - do one per outcome, per time point*
Name of outcome and measure:
Time point (for example, post-treatment, six months, one year):

| | Pre-test | | | Post-test | | |
|---|---|---|---|---|---|---|
| | Number * | Mean ** | SD | Number * | Mean | SD |
| **Experimental** | - | - | - | - | - | - |
| **Control** | - | - | - | - | - | - |

*(* Be sure to think about intention-to-treat (ITT) when writing number (N) in: have trialists already adjusted results?)*
*(** Check whether endpoint or change data have been used)*

'Risk of bias' judgements - provide quotation and page number, then judgement

| Item | Judgement | Description |
|---|---|---|
| Adequate sequence generation? | Yes / Unclear / No | - |
| Allocation concealment? | Yes / Unclear / No | - |
| Blinding of outcome assessment? | Yes / Unclear / No | - |
| Incomplete outcome data addressed? | Yes / Unclear / No | - |
| Free of selective reporting? | Yes / Unclear / No | - |
| Other sources of bias? | Yes / Unclear / No | - |

Power calculation?
Finally:
Items to correspond with trial investigators about?
Date contacted investigators:
Response:

## HISTORY

Protocol first published: Issue 1, 2017

| Date | Event | Description |
|---|---|---|
| 7 November 2016 | Amended | Subgroup analysis extended in-line with comments in text. |

(*Continued*)

| | | |
|---|---|---|
| 25 April 2016 | Amended | Background cut down, response to comments completed throughout, new section on how the intervention might work |
| 2 July 2008 | Amended | Minor update: 31/07/07 |
| 2 July 2008 | Amended | Converted to new review format. |
| 2 July 2008 | New search has been performed | This is an update of the 2003 review. |
| 26 July 2007 | New citation required and conclusions have changed | Substantive amendment |

## CONTRIBUTIONS OF AUTHORS

Professor James Law has overall responsibility for this review. All authors have contributed to the writing of this protocol.

## DECLARATIONS OF INTEREST

James Law (JL) - is an author on one included study (Law 1999) and one excluded study in the previous version of this review (Kot 1995), and has published a non-Cochrane review in this area (Law 1997). For those studies in which JL is involved, the two other authors (JAD and JJVC) will assess the eligibility of studies for inclusion, complete 'Risk of bias' assessments and extract data. JL received £10,000 funding from the Nuffield Foundation for the previous version of this review (Law 2003a); the protocol of which was also published (Law 2003b). JL is an Editor for CDPLP.

Jane A Dennis (JAD) - is the Feedback Editor for CDPLP.

Jenna JV Charlton (JJVC) - none known.

## SOURCES OF SUPPORT

### Internal sources

- Newcastle University, UK.

Office base and support for the review to be carried out during office hours

### External sources

- No sources of support supplied

## NOTES

This review is coregistered within the Campbell Collaboration (Law 2005b), as is the published protocol (Law 2003c).

This review supersedes the review by Law J, Garrett Z, Nye C. Speech and language therapy interventions for children with primary speech and language delay or disorder. Cochrane Database of Systematic Reviews 2003, Issue 3. Art. No.: CD004110. DOI: 10.1002/14651858.CD004110 (Law 2003a).